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Re-evaluation Note REV2012-04

Re-evaluation Project Plan for Sodium Omadine

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Introduction

In Canada, sodium omadine is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they continue to meet standards of modern science and current policy established to protect human health and the environment. Under the authority of section 16 of the *Pest Control Products Act*, the registrant of sodium omadine was notified of the initiation of the re-evaluation of sodium omadine. Following this, the registrant of the sodium omadine technical grade active ingredient in Canada indicated their intention to support all uses included on the label of the commercial class product in Canada, except the use in aqueous synthetic fiber lubricants (spin finishes). This Re-evaluation Note outlines a project plan and timeline for review, as well as summarizes the anticipated area(s) of focus related to the re-evaluation of sodium omadine.

Sodium omadine is a broad spectrum antimicrobial that has been registered in Canada since 1995. Sodium omadine is currently registered as a material preservative to inhibit the growth of bacteria and fungi in a number of different industrial and consumer products (Use-site Category 18). There is one registered sodium omadine end-use product which is formulated as a solution, to be applied during the manufacturing process or directly to solutions for preservation, either by open pour or metered pump.

The project plan discussed below outlines the anticipated area(s) of focus and risk assessments required to complete the re-evaluation of sodium omadine. Should additional information become available during the re-evaluation period that affects the regulatory status of sodium omadine, the Agency will reconsider the area(s) of focus and risk assessments required. Currently, a proposed re-evaluation decision for sodium omadine is anticipated to be published for consultation in Winter 2013.

Re-evaluation Project Plan

Human Health Risk Assessment

- A review of sodium omadine toxicology was conducted in support of the initial registration, and was re-visited in 2010 in support of a use expansion request. The toxicology database for sodium omadine is considered complete. *Pest Control Products Act* hazard considerations will be addressed.
- Occupational and residential risk assessments previously conducted to support the registered uses will be updated where warranted to ensure that they continue to meet the standards of modern science and reflect current policy.
- Based on the registered use pattern for sodium omadine, a dietary exposure assessment is not required.

Environmental Risk Assessment

- Based on the registered use pattern, environmental exposure to sodium omadine is expected to be limited.
- Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements and the Toxic Substances Management Policy (TSMP) will be considered.

Value

- The value of sodium omadine will be considered. The viability of alternatives will be examined if risks of concern are identified.

Data Requirements

- No additional data requirements have been identified for sodium omadine at this time.

Anticipated Timeline for Re-evaluation

- A proposed re-evaluation decision for sodium omadine is anticipated to be published for consultation in Winter 2013.

Additional Information

PMRA documents can be found on our website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service.
Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca